**A 25 mm length is not the same as a 12 or 10 mm focal length or 8 mm scan depth**

It is axiomatic that for a reference to anticipate a claim, the reference must teach every element of the claim. Applicant contends that it is self evident that 25 mm is not the same as 12 mm. Simply stated, a 12 mm focal length does not and cannot anticipate a 25 mm focal length. The Examiner's allusion to the need to prove "unexpected results" is confused, as unexpected results do not relate to a determination of anticipation.

Furthermore, one of skill in the art would comprehend the very different nature of a focal length of 12 mm and 25 mm. The average distance in the human eyeball from the surface to the retina is 24 mm. *See* Exhibit 1. A device with a focal length of 12 mm cannot reach the retina or the macular regions of the eyeball, which prior to applicant's invention, were not examinable by an ultrasound transducer. As applicant has stated under declaration, that prior art devices had a "penetration limit at a depth of 4 mm to 5 mm in tissue." Specification, at 7, line 5. Therefore, one of skill in the art would not understand of a focal length of 12 mm and 25 mm to be the same.

Finally, Silverman states that the scan depth is "approximately 8 mm," which as discussed below is not sufficient to reach the posterior segment of the eye. Silverman et at., *Three-dimensional High-Frequency Ultrasonic Parameter Imaging of Anterior Segment Pathology,* Ophthalmology, May 1995, at 837, col. 2, bottom.

**A penetration of 4 to 5 mm is deep enough only to examine the eye's anterior segment**

Applicant contends that the Examiner is incorrect when he opines that "4-5 mm is considered *deep enough* with respect to the eye." As shown in Exhibit 1 the average cornea is 0.449 mm deep, the distance between the corneas to the lens is 2.794 mm, the depth of the lens is 4.979 mm. Adding these distances together, one would understand that a depth of 5 mm is only sufficient to penetrate to approximately the midsection of the lens. Thus, a depth of 5 mm is completely insufficient to reach, for example, the macular region, which is approximately 24 mm from the front surface of the cornea. *See* Exhibit 2, Figure 1 (indicating location of the macular region).

**The anterior segment of the eye is different than the posterior segment**

As is well recognized in the art, the anterior segment of the eye and the posterior segment, are discrete parts of the eye, with significantly different anatomies. The anterior segment of the eye includes the cornea, anterior chamber, iris, and lens. *See* Exhibit 3.

The posterior segment of the eye lies behind the lens. *See* Exhibit 4. The posterior segment of the eye includes the vitreous humor (fluid) that fills the anterior chamber and lies between the lens and, the rear of the eye, which includes the retina and the macular region. Until the present invention, vitreous humor has in part prevented ultrasound imaging of the posterior portion of the eye.

**Silverman's device is not for deep penetration**

Without citing any support from the Silverman references, the Examiner states that the Silverman device is adapted for deep penetration. Applicant contends that a careful review of the Silverman references do not support this allegation. Throughout both references, Silverman only discusses the imaging of the anterior segment of the eye, and never mentions imaging of the posterior segment. Applicant contends that the meaning of "deep penetration" as would be understood by one of skill in the art is penetration that would be adapted to explore the posterior segment of the eye.

In the article entitled *Three-dimensional High-Frequency Ultrasonic Parameter Imaging of Anterior Segment Pathology,* (emphasis added), the first line of the abstract defines the purpose to be "imaging of anterior segment pathology." Silverman et al., *Three-dimensional High-Frequency Ultrasonic Parameter Imaging of Anterior Segment Pathology,* Ophthalmology, May 1995, at 837 (emphasis added). The conclusion of the abstract states "[t]hree-dimensional imaging of the *anterior segment* with high-frequency ultrasound allows construction of perspective images, which adds to the already significant clinical use of individual high-resolution B-mode images." *Id.* (emphasis added). Moreover, as shown in Figures 2-5 of this reference, the Silverman device is only able to scan areas in the anterior segment of the eye, such as the cornea and surface of the lens.

US Patent No. 5,776,068 only discusses anterior examination of the eye and provides no explicit or implicit statement on posterior examination. For example, in the abstract line 1, "[a]pparatus is provided for high frequency ultrasound examination of the anterior segment of a patient's eyes," or c. 2, ll. 14-17, "[a]ccordingly, it is an object of this invention to provide an improved ultrasound imaging system, particularly adapted to 3-D imaging of corneal structures and the anterior segments of the eye." (Emphasis added). In fact, the word "segment" is mentioned 18 times in the patent, and only in the context of being an anterior segment.

**The art explicitly states the posterior pole cannot be examined**

Applicant attaches hereto as Exhibit 5 an art recognized authority that provides a summary of ultrasound biomicroscopy of the eye. Charles Pavlin & Stuart Foster, *Ultrasound Biomicroscopy of the Eye*, at 223 (Ultrasound of the Eye and Orbit, Sandra Frazier Byrne & Ronald L. Green eds. 2002) (Exhibit 5). Throughout this article, various applications of ultrasound biomicroscopy are discussed, but all the applications are for imaging the anterior segment of the eye and none are for imaging of the posterior segment. In fact this article explicitly states that posterior imaging of the eye is not possible "[e]xamination of structures such as the posterior pole of the eye is not possible at the present time." *Id.* at 226 (emphasis added).

As further evidence to support the inability of the prior art devices to use ultrasound to examine the posterior of the eye, applicant wishes to direct the examiner to the following quotes, with emphasis added.

1. Silverman: "Three Dimensional High Frequency Ultrasonic Parameter Imaging of Anterior Segment, Ophthalmology, 1995; 102:837-843" (of record).

- Page 837, column 2 : "50 to 100 MHz range currently are being used to examine the anterior segment. Ref. 1 : Pavlin et al. Clinical use of ultrasound biomicroscopy. Ophthalmology 1991; 98: 287-95" (see the comments from the princeps article of the ultrasound biomicroscopy)
- Page 838, column 1, line 1 : "(the use of high frequency transducer) is limited in applicability due to the rapid increase in acoustic attenuation with increasing frequency. The anterior segment is a special case... High frequencies thus can be used to the greatest advantage for imaging anterior segment structures.

2. Pavlin : "Subsurface ultrasound microscopic imaging of intact eyes" Ophthalmology 1990 ; 97 : 241-250 (of record).

- Abstract, line 4 : "These devices are capable of producing images to a depth of 4 mm".
- Page 244, column 1, line 5 : "higher frequency ultrasound results in greater resolution and more accurate measurement, but at the expense of decreased penetration".

- Page 244, column 2, line 14 : "Tissue penetration is confined to approximately 4 mm".

- Page 250, column 1, line 1: "It is unlikely that penetration can be increased enough to image the posterior globe".

3. Pavlin: "Ultrasound Biomicroscopy in assessment of anterior scleral disease, Am J Ophthalmology. 1993 ; 116:628-635" (Exhibit 6)

- Page 629, column 1, line 5 : "penetration is limited to 4 to 5 mm, which is adequate to display the majority of the anterior segment of the eye".

- Page 629, column 1, line 18 : "penetration is not adequate to cross the globe to examine the posterior sclera".

4. Foster : "Ultrasound backscatter microscopy of the eye in vivo IEEE ultrasonic symposium : proceedings 1481-1484 (90CH2938-9) 1990" (Exhibit 7)

- Page 1481, column 1, line 11 : "Microscopic images of the normal structures of anterior segment..."

- Page 1481, column 1, line 28 : "a maximum depth of penetration of approximately 5 mm."

5. Pavlin: "Ultrasound Biomicroscopy of anterior structures in normal and glaucomatous eyes, Am. J. Ophthalmol. 1992; 113:381-389" (Exhibit 8)

- Page 1, column 2, line 31 : "In general, higher frequency transducers are used for fine resolution of more superficial structures and lower frequency transducers are used when depth of penetration is important".

- Page 1, column 2, line 39 ; "Tissue penetration is approximately 4mm".

6. Pavlin & Foster: "Ultrasound Biomicroscopy of the eye ; basic physics of high-frequency ultrasound imaging. 1995 Springer-Verlag New-York: 13-15" (Exhibit 9)

- Page 14, column 1, line 13 : "the penalty to be paid for this increase in resolution is loss of penetration";

- Page 14, column 1, line 21 : "For the 60 MHz system, penetration is only 5 mm"

- Page 14, Figure 1.14 : "Plot of penetration versus frequency under realistic conditions. Increased resolution at elevated frequencies is accompanied by reduced

penetration due to increased losses in the tissues... only 5 mm can be penetrated at 60 MHz"

- Page 15, column 1, line 9 : "Because losses due to attenuation increase almost linearly with frequency, the total imaging depth is significantly reduced, leading to fields of view of 4-5 mm".

7. Tello: "Ultrasound Biomicroscopy in pseudophakic malignant glaucoma, Ophthalmology 1993:100 ; 1330-1334 (Exhibit 10)

- Page 1333, column 2, line 9 : "Tissue penetration is approximately 4 mm".

**The International Examiner recognized that the imaging of the posterior of the eye was both novel and had inventive step**

Although applicant understands that the US Examiner is not legally bound by the IPER, applicant at least wishes to emphasize that the novelty and non-obviousness of the focal length capable of examining the back of the eye were recognized during the International Examination. Applicant reproduces below this portion of the IPER.

> None of the documents cited in the search report mentions the possibility of using a transducer with a long focal length. The effect obtained with such focusing, i.e. the possibility of exploring with precision at great depth so as to be able to explore the posterior segment of the eyeball is considered as being unexpected since the prior art would appear to discourage the person skilled in the art from exploring using high frequency ultrasound (50 MHz to 100 MHz), i.e. at high resolution, when seeking to explore the posterior segment of the eyeball. For example, the authors of D1 [the Silverman article] and D2 [article by Palvlin] state explicitly that it is impossible to explore the posterior segment with a transducer having a high excitation frequency, i.e. lying in the range 50 MHz to 100 MHz (see D1, page 837, right-hand column and page 383, left-hand column, first paragraph; D2, page 250; and in the present description page 7, lines 12 to 19.)

**Rejections Under 35 USC §103(a)**

Claims 14-16 and 20-22 are rejected under USC §103(a) as being unpatentable over Zeimer (US 4,883,061). Applicant respectfully traverses the rejection and urges its withdrawal, as the Examiner has not established a prima facie case of obviousness. In contrast to the present invention, Zeimer uses a laser to measuring the thickness of eye components. A laser is not analogous to or combinable with an echographic exploration device. Therefore, a combination of this reference and the Silverman references neither

teaches every element of the claims nor provides a reasonable expectation of success nor a suggestion of how one could use ultrasound to exam the posterior of the eye.

Furthermore, as applicant has previously stated, a device using a beam of light is not able to penetrate through the pars plana. That means that such a system can only be used for investigating the posterior part of the retina of the eye through the pupil. Therefore, the posterior segment of the eyeball can only be investigated in a very limited manner, i.e. only on the macular region placed in the axis of the pupil.

Moreover, such a device based on the use of a beam of light cannot be used in specific cases such as when the transparency of the vitreous humor of the eye is affected for example, by internal bleeding, or in case of cataract.

Claims 3, 4, 6-9 and 23 are rejected under USC §103(a) as being unpatentable over Silverman et al in view of Coleman et al (US 5,331,962) or Reinstein et al. (US 5,293,871). Applicant traverses this rejection. Again these references are only directed to ultrasonic biometer images had only been obtained on the corneal layer, *i.e.*, the anterior segment of the eyeball. Therefore, the combination of any of these references does not teach every element of the claims nor provides a reasonable expectation of success nor a suggestion of how one could use ultrasound to examine the posterior of the eye.

## CONCLUSION

In view of the above remarks and amendments, it is respectfully submitted that this application is in condition for allowance. Early notice to that effect is earnestly solicited.

The Examiner is invited to telephone the undersigned at the number listed below if the Examiner believes such would be helpful in advancing the application to issue.

Respectfully submitted,

December 27, 2002
Date

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**Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.**